REMARKS

Applicants have amended the claims in the application without prejudice or disclaimer to more particularly define the invention taking into consideration the outstanding Official Action. Applicants have amended the claims to make some obvious modifications to provide proper antecedent basis for the claim subject matter and obviate the rejections in this regard.

In a addition, a new claim set, claims 36-43, paralleling the rejected claims has been added to remove any alleged new matter and in an effort to expedite prosecution to an early indication of allowable subject matter. The new matter and rejections under 35 USC 112, have been carefully considered but are most respectfully traversed.

Applicants most respectfully submit that all the claims now present in the application are in full compliance with 35 U.S.C. §112 and are clearly patentable over the references of record.

The rejection of the claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been carefully considered but is most respectfully traversed in view of the amendments to the claims. Accordingly, it is believed that this rejection has been obviated and the withdrawal of same is most respectfully requested.

Applicants have carefully considered the rejection of claims 29-32 under 35 U.S.C. 112, second paragraph, as indefinite. These claims have been appropriately amended to remove any ambiguity as noted by the Examiner in this rejection. The specific phrases have been modified and it is therefore requested that these rejections be withdrawn.

The rejection of claim 28 is presumed to be also rejected under 35 U.S.C. 112, second paragraph. Claim 28 has been amended to provide the proper antecedent basis by removal of the word "the" at line 4 as indicated on page 3 of the Official Action.

Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The rejection of claims 28-35 under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims has been carefully considered but is most respectfully traversed.

In this regard, the Examiner is again most respectfully directed to MPEP § 2164.01 Test of Enablement which provides the standard for enablement. As noted therein, any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of Mineral Separation v. Hyde, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also United States v. Telectronics, Inc., 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S.

947 (1987); and Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). Determining enablement is a question of law based on underlying factual findings. In re Vaeck, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). Applying this standard it is evident that the claims are enabling to one of ordinary skill in the art without undue experimentation.

Applicants wish to note that the Examiner's opinion in paragraph 2 of page 5, the use of a 1:1 ratio of the expression transgene plasmid results from the 2 transgenes which the inventor uses have similar length (hFIX about 4.5kb and pLF about 4.7kb); therefore, after several attempts, Applicants found that 1:1 is the best ratio to produce the transgenic swine. This is the best mode as set forth in the specification but one of ordinary skill in the art would appreciate that other ratios may be used. To restrict the claims to the best mode is not proper and would deny the Applicants reasonable protection of their invention.

Referring to the Examiner's opinion in paragraph 2 of page 6, owing to transgenic animal technology progress, extremely since 1998, it can be stated that one of ordinary skill in the art would know that gene expression efficiency can be improved by applying pre-mRNA processing, post- mRNA processing or other modification technology. However, under the same genetic background (swine), the inventor's strategy has substantially and steadily raised Lactoferrin concentration (referring to Fig. 4).

According to example 5, the content of human clotting factor IX in per milliliter of porcine milk collected ranged from 200~500g, which is 40~100 times the level in normal human plasma (5 g/ml) and was maintained at a stable level throughout the 28 days of lactation. The method disclosed in the present invention can successfully transfer two or more recombinant genes into swine, and the transgenes can express large quantity of protein continuously and stably throughout the lactating period of the swine. In comparison with prior transgenic technology where the expression of

recombinant protein tends to drop significantly or even stops into the 11th day of lactating period, this invention shows non-obviousness.

Moreover, the offsprings of transgenic mammal according to this invention also carry the transgene, and the expression level of the recombinant genes is comparable to that I the first generation, which further illustrates the advantage of the present invention. As regards the Examiner's statements, Applicants can conclude that the characteristics of pLF gene, mammal gland specific promoter and swine's gene background as well as the inventor's strategy can lead to the progression.

Applicants also most respectfully submit that the written description requirement does not require that the exact language set forth in the claim be recited in the specification. The specification needs to reasonably convey to one of ordinary skill in the art that Applicants were in possession of the invention at the time the application was filed. Clearly, one of ordinary skill in the art would understand the expression "genetic insert" as inclusive of the plasma described in the present invention. Similarly, the phrase "synchronized recipient" would also be clearly understood by one of ordinary skill in the art to which the invention pertains as this synchronization is necessary for the transference as would be appreciated by one skilled in the art.

Similarly, one of ordinary skill in the art would appreciate that additional methods for transferring the expression "plasmid by means other than the gene injection and embryonic implantation" are known to one skilled in the art.

The Examiner is correct that Applicants cannot point to a particular line and page number in the specification which specifically recites the words which are considered not to comply with the written description requirement. However, the test is not whether or not the specific words are present but whether or not the invention as claimed is clearly conveyed to one of ordinary skill in the art taking into consideration the level of skill. Accordingly, it is most respectfully requested that this aspect of the rejection be withdrawn.

The rejection of claims 28-30 and 32-35 under 35 U.S.C. 112, first paragraph, with respect to enablement using only a 1:1 mixture of plasmids has been carefully

considered but is most respectfully traversed. While it is agreed that this is a preferred embodiment of the invention, the statute does not require that Applicants be restricted to this specific ratio. Clearly, one of ordinary skill in the art would appreciate that various ratios can be used to achieve the results, without undue experimentation. Moreover, there are limitations in claims which require that the appropriate results are achieved and therefore a ratio outside the range which achieve this would not be included in the claims. Accordingly, it is most respectfully requested that this rejection be withdrawn.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

BACON & THOMAS, PLLC

By: Richard E. Fichter

Richard E. Fichter
Registration No. 26,382

625 Slaters Lane, 4th Fl.
Alexandria, Virginia 22314
Phone: (703) 683-0500
Facsimile: (703) 683-1080

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